

REMARKS

This document is filed in reply to the Office Action dated July 3, 2007 (“Office Action”). Applicant has amended claim 1 to include all of the limitation of claim 4, now cancelled. Note that claim 4 depends from claim 3, which in turn depends from claim 1. Merger of claim 4 into claim 1 has necessitated cancellation of claim 3 and change of dependencies of claims 5, 9, and 10. Further, in view of cancellation of claim 3, claim 11, which depends from claim 3, has been rewritten in independent form to include all limitations of claims 3 and certain limitations of claim 4. Claims 6, 7, 15, 16, 17, 36, and 45 have also been amended to promote clearly. Claims 53-61, which cover non-elected subject matter, have been cancelled.

Upon entry of the above amendments, claims 1, 2, and 5-52 will be pending. Among them, claims 1, 2, and 5-21 have been under examination. Applicant respectfully requests that the Examiner also consider claims 22-52, which, together with claims 1-21, are included in Group I set forth in the restriction requirement dated November 15, 2006. Note that in response to that restriction requirement, Applicant elected the claims of Group I for prosecution, identifying claims 3-11 as single species.<sup>1</sup>

Rejection under 35 U.S.C. § 112, second paragraph

Claim 16 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite. More specifically, it is the Examiner’s position that the Markush terminology in claim 16 is improper. Applicant has amended claim 16 and respectfully requests withdrawal of this rejection.

Rejection under 35 U.S.C. § 102(b)

The Examiner rejected claims 1-3, 12-14, 15-19, and 21 for anticipation on three grounds. Applicants address them separately below.

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<sup>1</sup> Applicant elected Group I, pointing out that this group included claims 1-21. Of course, Group I also includes claims 22-52. See page 2section 1, subsection I of the restriction requirement. Of note, claim 1 is an independent claim, from which claims 2-21 depend. By specifically identifying claims 1-21, Applicant meant to elect claims 3-11, subsumed by claim 1, as single species. See page 3, section 5, subsection a of the restriction requirement.

I

The Examiner rejected claims 1-3, 12-14, 16-19, and 21 as anticipated by Su et al., U.S. Patent Application 20020183830 (“Su”). See the Office Action, page 3, first paragraph. Claim 3 has been cancelled. Among the rejected claims, only claim 1 is independent.

Applicants have amended claim 1. Claim 1, as amended, covers a method of making a medical apparatus (e.g. an expandable stent) that includes both primary loops and secondary loops. In the method of amended claim 1, a secondary loop is formed on a primary loop by using a clip to grip a portion of the primary loop and rotate the clip to twist the portion.

Su describes a method of making an expandable stent that includes primary loops and secondary loops, i.e., lobes 20 and lobs 30, respectively, as shown in Fig. 1.

Referring to Fig. 1 again, Su teaches using a unique fixture including a central cylindrical mandrel and three cylindrical side posts to manually wind a fiber cord to form primary loops and secondary loops. More specifically, the primary loops and secondary loops, according to the Su method, are formed by “[w]inding the cord around the mandrel, and successively looping the cord around the posts moving downward toward the base until [ ] rotations of the mandrel have been completed.” See page 3, paragraph (0021), lines 3-6.

In short, Su clearly does not teach using a clip for twisting a primary loop to form a secondary loop as required by amended claim 1.

For at least this reason, Applicant submits that claim 1 is not anticipated by Su. Nor are claims 2, 12-14, 16-19, and 21, all of which depend from claim 1.

II

The Examiner rejected claims 1-3, 12, 16-19, 21 as anticipated by Mariant et al., U.S. Patent 5,639,277 (“Mariant”). See the Office Action, page 3, second paragraph. Again, claim 3 has been cancelled and only claim 1 is independent.

As discussed above, in the method of amended claim 1, a secondary loop is formed on a primary loop by using a clip.

Mariant describes a method of making a vasoocclusive coil that includes primary loops and secondary loops. A schematic side view of the vasoocclusive coil, including primary (large) loops and secondary (small) loops, is shown in Fig. 1. A procedure for making this coil is described at column 8, lines 8-19 and illustrated in Figs. 15A-15C. More specifically, a coil 150 is first wound onto a first mandrel 152 (Fig. 15A), then threaded with a second mandrel 154 (Fig. 15B), and, finally, threaded with a third mandrel 158 to complete the procedure (Fig. 15C). More specifically, the first mandrel is used for making the primary loops, the second mandrel is used for making the secondary loops, and the third mandrel is used for configuring the final shape of the stent. Mariant clearly does not teach using a clip to form secondary loops on primary loops.<sup>2</sup>

In view of the above remarks, Applicant submits that claim 1, as well as claims 2, 12, 16-19, and 21 dependent from it, is not anticipated by Mariant.

### III

The Examiner rejected claims 1-2, 12, 15-19, and 21 as anticipated by Stevens et al., U.S. Patent 6,497,724 (“Stevens”). See the Office Action, pages 3-4, crossover paragraph.

Claim 1, the only independent claim, has been discussed above. Again, the method of amended claim 1 requires that a secondary loop be formed on a primary loop by using a clip.

Stevens describes a method of making a spiral structure that includes spiral units 11 and joints 15. See Fig. 11B. The spiral units 11 and joints 15 correspond respectively to the primary loops and secondary loops recited in claim 1. More specifically, joints 15 are spring joints (column 4, lines 10-14), each having the shape of a loop (Fig. 11B) corresponding to the secondary loop recited in claim 1. Each spiral unit 11, which includes a number of joints 15 (Fig. 11B) corresponding to the primary loop recited in claim 1. Stevens does not teach or suggest forming a secondary loop on a primary loop

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<sup>2</sup> Mariant also discloses other embodiments of a vasoocclusive coil that include both large loops and small loops (Figs. 3, 5-6, 7, 9-11). All loops in these embodiments are formed using mandrels. Applicants would like to point out that the embodiment shown in Fig. 11, the large loops are separate from and independent of the small loops. In other words, there are no secondary loops on primary loops, as is the case in the medical apparatus prepared by the method of claim 1.

using a clip as required by amended claim 1.<sup>3</sup>

For the reasons set forth above, Applicant submits that neither claim 1 nor its dependent claims 2, 12, 15-19, and 21 are anticipated by Stevens.

### Rejection under 35 U.S.C. § 103

The Examiner rejected each of claims 4, 9, 11, and 20 for obviousness on one of the three grounds. Applicants address them separately below.

#### I

Claims 4 and 9 are rejected as being obvious over Su in view of Hyodoh et al., U.S. Patent 6,409,750 (“Hyodoh”). See the Office Action, page 3, penultimate paragraph. Claim 4 has been cancelled and all of its limitations incorporated into claim 1. Applicants will therefore discuss claim 1, instead of claim 4. Note that claim 9, originally dependent from claim 4, has been amended so that it now depends from claim 1.

Claim 1, as amended, covers a method of making an expandable stent that includes a coil having primary loops and secondary loops. In the method of amended claim 1, the secondary loops are formed using a clip. Claim 9 covers a preferred version of the method, i.e., moving the coil relatively to the clip.

As previously discussed, Su does not teach or suggest using a clip to form a secondary loop on a primary loop, let alone moving a coil relatively to the clip. In the Su method, primary loops and secondary loops of a stent are formed by winding a fiber cord on a central mandrel and on side posts. Referring to Figs. 3A-3B, when stent 100 is caused to expand, secondary loops 130 merge into primary loop 120, thereby greatly increasing “the final expanded stent diameter.” See pages 3-4, crossover paragraph (0030), last sentence.

Hyodoh describes a method of weaving wires for making a self-expanding stent. It teaches using a tool 712 to form closed structures at the ends of the wires after the weaving process is completed. See Fig. 41A and column 17, lines 18-24. Hyodoh points

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<sup>3</sup> Other than Fig. 11B of Stevens, the Examiner’s relies on Figs. 15A-15 C of that reference. However, there are no Figs. 15A-15C in Stevens.

out that the closed structures are less likely to cause damage by the stent than free wire ends, in which the damage includes perforations or penetrations. See column 7, lines 43-47. In other words, Hyodoh teaches using a tool to form closed structures 45 at the end of wires (Fig. 1C) to minimize damage caused by the stent made of the wires. To achieve this, the closed structures taught by Hyodoh have to be maintained throughout the use of the stent. In any event, these closed structures, unlike the secondary loops described in Su, cannot contribute to greater expansion of a stent after it is placed at a target site and caused to expand. In other words, the secondary loops described in Su are not analogous to the closed structures described in Hyodoh.

In short, Su and Hyodoh teach very different subject matter, i.e., increasing expansion of a stent vs reducing damage caused by a stent. A skilled person in the art would not have been motivated to combine these two references to arrive at the method of claim 1. In other words, a skilled artisan, with the teachings of Hyodoh, would not have modified the Su method to make secondary loops in the manner required by amended claim 1.

Applicant therefore submits that neither claim 1, as amended, nor claim 9 dependent from it, is rendered obvious by Su and Hyodoh, either alone or in combination. Applicant would like to point out that claim 9 is nonobvious over Su in view of Hyodoh on an additional ground -- both references are silent on the "moving a coil relative to the clip" feature required by this claim.

## II

Claim 11 is rejected as being unpatentable over Su in view of Bolea et al., U.S. Patent 6,821,291 ("Bolea"). See the Office Action, pages 4-5, carryover paragraph.

Amended claim 11, an independent claim, covers a method of making a medical apparatus that includes both primary loops and secondary loops. More specifically, a hook is used to grip a portion of a primary loop and rotate the hook to twist the portion to form a secondary loop on the primary loop.

As discussed above, Su describes a method of making a stent having both primary loops and secondary loops; namely, forming primary loops and secondary loops

using a unique fixture that includes a central cylindrical mandrel and three cylindrical side posts, not using a hook, for winding a fiber cord to form primary loops and secondary loops. As discussed above, the secondary loops are so designed that they enable the stent to expand to a greater degree at a target site.

The Examiner has clearly misread Bolea. Contrary to his belief, this reference does not teach using “a hook to manufacture [a] loop.” See the Office Action, page 5, lines 3. Rather, it describes a method for removing a stent that is encircled by a lasso from a target site by first twisting the lasso to collapse the stent. More specifically, Bolea teaches that “a collapsing element can [] be configured as a lasso 80 situated around the circumference of a proximal end 22 of a stent 10.” See Fig. 8 and column 6, lines 52-54. In other words, the lasso is around the stent, and is therefore not part of the stent. Put differently, the stent does not include the lasso.

In short, Su teaches making a stent that includes secondary loops that allow for greater expansion of a stent at a target site, and Bolea teaches twisting a lasso around a stent to collapse the stent to facilitate its removal from a target site. As Su and Bolea provide diametrically opposite teachings, a skilled person in the art would not have been motivated to combine these two references to arrive at the method of claim 11.

Further, Su teaches using a unique fixture as described above to form peripheral loops (corresponding to the secondary loop recited in claim 1) in a stent and Bolea teaches using a lasso (not corresponding to the secondary loop recited in claim 1) to collapse a stent. In other words, neither Su nor Bolea teaches or discloses a method of forming secondary loops by twisting a portion of the primary loop using a hook as required by claim 11. Applicant submits that, on this additional ground, these two references, either taken alone or in combination, do not render claim 11 obvious.

### III

Finally, the Examiner rejected claim 20 as unpatentable over Su. See the Office Action, page 5, second paragraph.

Claim 20, dependent from claim 1, covers a method of making a secondary loop on a primary loop by using a clip to grip a portion of the primary loop and rotate the clip

to twist the portion to form the secondary loop, the secondary loop including a partially open curve that does not form a closed loop.

As discussed above, Su describes a method of forming primary loops and secondary loops by using a unique fixture. It teaches using a unique fixture including a central cylindrical mandrel and three cylindrical side posts for winding a fiber cord to form primary loops and secondary loop. Su does not teach using a clip to form secondary loops.

Given these substantial difference between this unique fixture taught in Su and the clip required by the method of claim 20, claim 20 is clearly not rendered obvious by this reference. Applicants therefore respectfully request that the Examiner withdraw this rejection.

#### Allowable claims 5-8 and 10

The Examiner concluded that claims 5-8 and 10 cover allowable subject matter and would be allowable if rewritten in independent form. See the Office Action, page 5, third paragraph.

Claims 5-8 and 10 all depend from claim 1. Applicants submit that claim 1, as amended, is now in condition for the reasons set forth above. It is therefore respectfully requested that the Examiner allow claims 5-8 and 10 in dependent form.

#### Claims 22-52 of elected Group II

The Examiner has not considered claims 22-52 of Group II set forth in the above-mentioned restriction requirement even though Applicant elected this group for prosecution.

Claims 22-48 all depend from claim 1 and are believed to be patentable for the same reasons provided above.

Claims 49 and 50, like claim 1, are also drawn to a method of making a medical apparatus that includes both primary loops and secondary loops. The methods of these two claims share a patentable feature; namely, they both require the step of “attaching

one or more longitudinal fibers to the primary loops to tend to maintain the relative positions of the primary loops in the small-dimension state and the large-dimension state.” This feature is not taught or suggested in any of the references relied on by the Examiner.

Claim 52 is also directed to a method of providing both primary loops and peripheral loops (i.e., secondary loops). The method of this claim bases its patentability on the step of “bending one of the peripheral loops towards a central portion of the coil to form an endoloop.” This step is neither disclosed or suggested in any of the cited references.

In view of the above remarks, Applicant submit that claims 22-52 are also in condition for allowance.

#### CONCLUSION

It is believed that all of the pending claims have been addressed. However, the absence of a reply to a specific rejection, issue or comment does not signify agreement with or concession of that rejection, issue or comment.

In addition, because the arguments made above may not be exhaustive, there may be reasons for patentability of any or all pending claims (or other claims) that have not been expressed.

Finally, nothing in this paper should be construed as an intent to concede any issue with regard to any claim, except as specifically stated in this paper, and the amendment of any claim does not necessarily signify concession of unpatentability of the claim prior to its amendment.

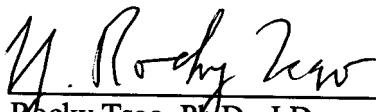
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The Petition for Extension of Time fee in the amount of \$60.00 is being paid concurrently herewith on the Electronic Filing System (EFS) by way of Deposit Account authorization. Please apply any other charges to Deposit Account No. 50-4189, referencing Attorney Docket No. 40008-002001.

Respectfully submitted

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